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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/053,869	01/24/2002	Hiroshi Nagasawa	NAGASAWA=7	5352
1444	7590 11/08/2006	•	EXAMINER	
BROWDY AND NEIMARK, P.L.L.C.			FORMAN, BETTY J	
624 NINTH S SUITE 300	TREET, NW	ART UNIT	PAPER NUMBER	
WASHINGTO	ON, DC 20001-5303		1634	
			DATE MAILED: 11/08/2006	5

Please find below and/or attached an Office communication concerning this application or proceeding.

		Application No.	Applicant(s)				
		10/053,869	NAGASAWA, HIROSHI				
	Office Action Summary	Examiner	Art Unit	-			
		BJ Forman	1634				
Period f	The MAILING DATE of this communication aport	pears on the cover sheet w	ith the correspondence address				
WHI0 - Exte after - If NO - Faile Any	IORTENED STATUTORY PERIOD FOR REPLICHEVER IS LONGER, FROM THE MAILING Densions of time may be available under the provisions of 37 CFR 1. TSIX (6) MONTHS from the mailing date of this communication. Operiod for reply is specified above, the maximum statutory period ure to reply within the set or extended period for reply will, by statut reply received by the Office later than three months after the mailing department term adjustment. See 37 CFR 1.704(b).	DATE OF THIS COMMUNI 136(a). In no event, however, may a will apply and will expire SIX (6) MON te, cause the application to become Al	CATION. reply be timely filed ITHS from the mailing date of this communication. BANDONED (35 U.S.C. § 133).				
Status							
1)[	Responsive to communication(s) filed on 18 A	August 2006.					
2a) <u></u> ☐	This action is <b>FINAL</b> . 2b)⊠ Thi	s action is non-final.					
3)[	Since this application is in condition for allowa						
	closed in accordance with the practice under	Ex parte Quayle, 1935 C.E	). 11, 453 O.G. 213.				
Disposit	ion of Claims						
4)🛛	Claim(s) 6,7 and 10-15 is/are pending in the a	application.					
	4a) Of the above claim(s) is/are withdrawn from consideration.						
5)	Claim(s) is/are allowed.						
6)⊠	☑ Claim(s) <u>6,7 and 10-15</u> is/are rejected.						
7)							
8)□	Claim(s) are subject to restriction and/o	or election requirement.	·				
Applicat	ion Papers						
9)[	The specification is objected to by the Examine	er.					
	The drawing(s) filed on is/are: a) ☐ acc		by the Examiner.				
	Applicant may not request that any objection to the		•				
	Replacement drawing sheet(s) including the correct		- ,				
11)	The oath or declaration is objected to by the E						
Priority (	under 35 U.S.C. § 119		•				
12)	Acknowledgment is made of a claim for foreigr	n priority under 35 U.S.C. §	; 119(a)-(d) or (f).				
a)	☐ All b)☐ Some * c)☐ None of:		, , , , , , , , , , , , , , , , , , ,				
	1. Certified copies of the priority document	ts have been received.					
	2. Certified copies of the priority document	ts have been received in A	pplication No				
	3. Copies of the certified copies of the prior	rity documents have been	received in this National Stage				
	application from the International Burea	• • • • • • • • • • • • • • • • • • • •	•				
* 5	See the attached detailed Office action for a list	of the certified copies not	received.				
	•						
Attachmen							
	e of References Cited (PTO-892) e of Draftsperson's Patent Drawing Review (PTO-948)	4) ∐ Interview S Paper Note	summary (PTO-413) s)/Mail Date				
3) 🔲 Inforr	mation Disclosure Statement(s) (PTO/SB/08)		oformal Patent Application				
	r No(s)/Mail Date	6) 🔲 Other:	_·				

#### **DETAILED ACTION**

#### Continued Examination Under 37 CFR 1.114

1. A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on 18 August 2006 has been entered.

# Status of the Claims

2. This action is in response to papers filed 18 August 2006 in which claims 6-7, 12 were amended, claims 8-9 were canceled and claims 14-15 were added. The amendments have been thoroughly reviewed and entered.

The previous rejections in the Office Action dated 21 July 2005 under 35 U.S.C. 112, first paragraph are withdrawn in view of the amendments. The previous rejections under 35 U.S.C. 102(b) and 103 are maintained for reasons set forth in the Advisory Action of 2 February 2006. All other rejections, not reiterated below, are withdrawn in view of the amendments. New grounds for rejection, necessitated by the amendments are discussed.

Claims 6-7 and 10-15 are under prosecution.

#### Claim Rejections - 35 USC § 102

3. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless -

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

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4. Claims 6-7, 9-11 and 14-15 are rejected under 35 U.S.C. 102(b) as being anticipated by Stein et al (WO 99/59722, published 25 November 1999).

Regarding Claim 6, Stein et al discloses a probe chip comprising a plurality of stacked and relatively flexible substrates, each having a plurality of through holes wherein the substrates are stacked to align the through-holes, a carrier filled in the through-holes wherein the carrier is porous relative to the substrate and probe molecules attached to the carrier (page 4, line 21-page 5, line 14, fig. 3-4 and 10) wherein the probe molecules attached to the surface of carriers in one groups are different from those in another group (page 8, line 17-page 9, line 23). Stein et al also teach the substrate is organic e.g. polyethylene (page 18, lines 10-19) as defined in the instant specification as organic (page 8, lines 37-38).

Regarding Claim 7, Stein et al discloses the method wherein the carrier is selected from the group consisting porous membrane (Fig. 7, page 21, line 23-page 22, line), non-woven fabric i.e. glass frit (page 26, lines 8-12) and a powder of porous glass i.e. 1µm beads (Fig. 10 and page 23, lines 10-page 25, line 11).

Regarding Claim 9, Stein et al discloses the method wherein the particle size of the glass bead is 1 to 100µm (page 25, lines 1-4).

Regarding Claim 10, Stein et al discloses the method wherein the probe is selected from peptides and oligonucleotides (page 8, lines 19-21).

Regarding Claim 11, Stein et al discloses the method wherein the substrates are stacked to align the through-holes of adjacent substrates in a liquid-tight manner so that liquid will not move laterally to adjacent through-holes e.g. o-ring (page 18, line 23-page 24, line 2) or sealing mechanism, Fig. 10 (page 23, lines 19-21).

Regarding Claim 14, Stein et al disclose the reaction probe chip wherein the porous glass has a particle size of 1 to 100 microns (page 25, lines 1-3).

Regarding Claim 15, Stein et al disclose a reaction probe chip comprising a substrate having a plurality of discrete through-holes; a first carrier (i.e. a first through-hole) made of

porous material having probes attached and a second carrier (i.e. a second through-hole) made of porous material having probes attached and a substrate having first and second through-holes filled with the first and second carrier (page 4, line 21-page 5, line 14, fig. 3-4 and 10).

5. Claim 15 is rejected under 35 U.S.C. 102(b) as being anticipated by Beattie (U.S. Patent No. 5,843, 767, issued 1 December 1998).

Regarding Claim 15, Beattie discloses a reaction probe chip comprising a substrate (e.g. glass or silicon, Claim 11) in the "form" of a sheet (i.e. planar, Fig. 1A) and having a plurality of discrete through-holes; a first carrier (i.e. a first through-hole) made of porous material having probes attached and a second carrier (i.e. a second through-hole) made of porous material having probes attached and a substrate having first and second through-holes filled with the first and second carrier (i.e. wafer having multiple through-holes, Fig. 1B).

### Claim Rejections - 35 USC § 103

- 6. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:
  - (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.
- 7. Claim 8 is rejected under 35 U.S.C. 103(a) as being unpatentable over Stein et al (WO 99/59722, published 25 November 1999) in view of Dusterhoft et al (WO 98/08954,

Regarding Claim 8, Stein et al discloses a probe chip comprising a plurality of stacked substrates, each having a plurality of through holes wherein the substrates are stacked to align the through-holes, a carrier filled in the through-holes wherein the carrier is porous relative to the substrate and probe molecules attached to the carrier (page 4, line 21-page 5, line 14), fig. 3-4 and 10) wherein the probe molecules attached to the surface of carriers in one groups are different from those in another group (page 8, line 17-page 9, line 23) wherein the carrier is a powder of porous glass i.e. 1µm beads (Fig. 10 and page 23, lines 10-page 25, line 11) and wherein the beads have perforations to provide greater surface area (page 24, lines 22-25) but is silent regarding the size of the perforation (i.e. pore size). However the claimed pore size of 0.1 to 0.5 µm was well known in the art as preferred particles at the time the claimed invention was made as taught by Dusterhoft et al (Column 3, lines 38-40; Column 11, lines 41-60). It would have been obvious to one of ordinary skill in the art at the time the claimed invention was made to apply the preferred pore size taught by Dusterhoft et al to the particles of Stein et al et al based on the preferred teaching Dusterhoft et al (page 11, lines 58-60) and for the expected benefit of providing increased surface area as desired by Stein et al (page 24, lines 22-25).

8. Claims 12-13 are rejected under 35 U.S.C. 103(a) as being unpatentable over Stein et al (WO 99/59722, published 25 November 1999).

Regarding Claims 12-13, Stein et al discloses a probe chip comprising a plurality of stacked substrates, each having a plurality of through holes wherein the substrates are stacked to align the through-holes, a carrier filled in the through-holes wherein the carrier is porous relative to the substrate and probe molecules attached to the carrier (page 4, line 21-page 5, line 14, fig. 3-4 and 10) wherein the probe molecules attached to the surface of carriers

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in one groups are different from those in another group (page 8, line 17-page 9, line 23). Stein et al also teach the substrate is plastic e.g. polyethylene (page 18, lines 10-19). Stein et al specifically teaches that exemplary substrates comprise polyethylenes (page 18, lines 13-19) wherein the substrates are tightly sealed to provide liquid-tight fluid flow-though the throughholes (page 22, line 20-page 23, line 25). While they do not specifically teach heat-sealing, the courts have stated that a product is defined by the product, not by the process by which is it made.

"[E]ven though product-by-process claims are limited by and defined by the process, determination of patentability is based on the product itself. The patentability of a product does not depend on its method of production. If the product in the product-by-process claim is the same as or obvious from a product of the prior art, the claim is unpatentable even though the prior product was made by a different process." In re Thorpe, 777 F.2d 695, 698, 227 USPQ 964, 966 (Fed. Cir. 1985) see MPEP 2113.

Furthermore, it is noted that In re Best (195 USPQ 430) and In re Fitzgerald (205 USPQ 594) discuss the support of rejections wherein the prior art discloses subject matter in which there is reason to believe inherently includes functions that are newly cited or is identical to a product instantly claimed. In such a situation the burden is shifted to the applicants to "prove that subject matter shown to be in the prior art does not possess characteristic relied on" (205 USPQ 594, second column, first full paragraph).

The claimed substrates are deemed equivalent or an obvious variation of the tightly sealed substrate of Stein et al.

## Response to Arguments

9. The claims have been amended to further define the substrate as "flexible" and to limit the carrier to "a porous glass powder" sandwiched between "polyethylene or polyester films". In papers filed 29 April 2005, Applicant asserted that the cited art did not teach flexible substrates. Because the claims were not limited to "flexible" substrate, the Office responded by stating that the assertion was not commensurate in scope with the claims. The Office further stated that even if the claims were limited to flexible substrate, they would not be free

of the cited art because flexibility is a relative term, such that any substrate material would be considered flexible when compared to some other less flexible substrate. Therefore, the substrate of Stein is flexible in comparison to some other less flexible substrate. Furthermore, Stein teaches a substrate is made of any glass or plastic e.g. polyethylene (page 18, lines 5-18, as cited in the final office action). Applicant has not provided any evidence demonstrating that the substrate of Stein is not flexible. Therefore, the amendment to Claim 6 does not define the claimed chip over the prior art.

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The amendment to Claim 7 limits the carrier to porous glass powder further limiting new Claim 14, which defines the particle size of the powder. As cited in the final office action, Stein teaches porous glass powder (fig. 10 and pages 23-25). However, the particle size of the glass powder was not previously considered. Therefore, new Claim 14 would require further search and consideration.

The amendment to Claim 12 further limits the plastic film to polyethylene or polyester. Stein teaches stacked polyethylene substrates having filters in the through holes as claimed (e.g. page 18 and fig. 7-11).

Applicant asserts that the claimed invention is different from that of Stein. Applicant states that the object of the instant invention is that the user can peel or separate the stacked chips to place them in contact with the sample. Applicant's comment is noted, however, the intended use of the device as described in the specification (or arguments) does not define the device over the prior art. Applicant further states that the preferred embodiment utilizes a substrate having the dimension of  $50 \times 30 \times 0.3$  mm-having through holes of 2mm-diameter. The embodiment is noted, however, the claimed device is not limited the preferred embodiment having these dimensions. Therefore, the argument is not commensurate in scope with the claims.

Applicant asserts that Stein does not teach porous glass having the claimed pore size. The assertion is noted, however the previously examined claims were not limited to the pore size of porous glass. Therefore the argument does not address the rejected claims. Furthermore, amended Claim 7 does not define pore size as asserted by Applicant. Therefore, the argument is not commensurate in scope with the rejected or amended claims.

Applicant asserts that the heat-sealing as recited in Claims 12-13 differs from the sealed substrates of Stein. The argument has been considered but is not found persuasive because Applicant has not provided any factual evidence of the asserted difference. Therefore, the argument is deemed unsupported arguments of counsel.

#### Conclusion

- 10. No claim is allowed.
- 11. Any inquiry concerning this communication or earlier communications from the examiner should be directed to BJ Forman whose telephone number is (571) 272-0741. The examiner can normally be reached on 6:00 TO 3:30.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Ram Shukla can be reached on (571) 272-0735. The fax phone number for the organization where this application or proceeding is assigned is (571) 273-8300.

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Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <a href="http://pair-direct.uspto.gov">http://pair-direct.uspto.gov</a>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

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Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to (571) 272-0547.

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For all other customer support, please call the USPTO Call Center (UCC) at 800-786-9199.

BJ Forman, Ph.D. Primary Examiner Art Unit: 1634 November 3, 2006